K021803

510(K) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS
Reflection Constrained Liner

Submitted By:	Smith & Nephew, Inc. Orthopaedic Division 1450 Brooks Road Memphis, TN 38116
	DEC 1 9 2002
Date:	May 31, 2002
Contact Person:	Janet Johnson Akil- Director, Regulatory Affairs
Proprietary Name:	Reflection Constrained Liner
Common Name:	Constrained Liner
Classification Name and Reference:	888.3310 - Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis - Class II
Device Product Code and Panel Code:	Orthopedics/87/KWZ

A. INTENDED USE

The Reflection Constrained Liner is a cemented or uncemented prosthesis intended to replace a hip joint. The Reflection Constrained Liner is intended for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, and intra-operative instability and for whom all other options to constrained acetabular components have been considered.

B. DEVICE DESCRIPTION

The Reflection Constrained Liner is used with existing appropriately sized Reflection Acetabular Shells. The Reflection Constrained Liner can be used with previously implanted femoral components, femoral heads (28 mm only) and Reflection Acetabular Shells such as in a revision case, or it may be used in primary cases and implanted along with the shell, head and stem. Any appropriately sized Reflection Shell may be utilized. Any stem may be used, provided a 28 mm metal femoral heads is used with the femoral component. Ceramic heads or skirted femoral heads of any material should not be used with the Reflection Constrained Liner.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The Reflection Constrained Liner is similar to the following: A) Reflection Acetabular Component B) Johnson & Johnson S-Rom Poly-Dial Constrained Liner C) Osteonics Constrained Acetabular Insert and D) Zimmer Triology Acetabular System.

D. SUMMARY OF TECHNOLOGICAL COMPARISON

The intended use, material, type of interface and design features of the Reflection Constrained Liner are similar to their predicate counterparts. The safety and effectiveness of this device are adequately supported by the substantial equivalence information, materials data, and testing results provided within this Abbreviated Premarket Notification. Such information was generated per data requirements outlined in the *Class II Special Controls Guidance Document: Hip Joint Metal Polymer Constrained Cemented and Uncemented Prosthesis; Guidance for Industry and FDA* dated April 30, 2002 and *Guidance Document for Data Requirements For Utra-high Molecular Weight Polyethylene (UHMWPE) Used In Bearing Surfaces For Orthopedic Devices*, dated September 7, 1997 and *Guidance Document for Testing Acetabular Cup Prosthesis* (dated May 1, 1995)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 2002

Ms. Janet Johnson Akil
Director, Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, Tennessee 38116

Re: K021803
Trade/Device Name: Reflection Constrained Liner
Regulation Number: 21 CFR 888.3310
Regulation Name: Hip joint metal/polymer constrained cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWZ
Dated: September 18, 2002
Received: September 20, 2002

Dear Ms. Akil:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number K021803

Device Name: Reflection Constrained Liner

Indications for Use:

The Reflection Constrained Liner is a cemented or uncemented prosthesis intended to replace a hip joint. The Reflection Constrained Liner is intended for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, and intraoperative instability and for whom all other options to constrained acetabular components have been considered.

The components subject of this notification are to be used with the Reflection Acetabular System, which is indicated for use with or without cement, and includes single use devices.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021803